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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,379	03/15/2004	Iddys D. Figueroa	200401492-1	3171

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EXAMINER	
MICHENER, JENNIFER KOLB	
ART UNIT	**PAPER NUMBER**
1762	

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,379	FIGUEROA ET AL.	
	Examiner	Art Unit	
	Jennifer K. Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 25-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,25,26- 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 3-7, and 26-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 of copending Application No. 10/801,380. Although the conflicting claims are not identical, they are not patentably distinct from each other because applying bioactive agent as dots to attain a selected target dissolution rate, as required by the co-pending application, inherently requires applying bioactive agent as dots in a desired dot topography to attain a selected target dissolution rate, as is required by the instant case.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1, 3, 4, 6, 26, and 29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6, and 29 of copending Application No. 10/801,381. Although the conflicting claims are not identical, they are not patentably distinct from each other because selecting the position of a first and second drop, as in the co-pending application inherently requires selection of the dot topography.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Both words in the phrases "relatively irregular", "relatively faster", and "relatively slower" are relative terms.

Additionally, this claim seems to call for both a faster and slower dissolution rate at the same time. This is unclear.

Claim Rejections - 35 USC § 102/103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-2, 4-7, 25-26, and 28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Voss et al. (4,322,449).

Voss teaches a method of applying a bioactive agent to a delivery substrate in the form of dots forming a desired geometrical pattern (abstract; throughout; col. 5, liens 35-37). Voss teaches the control of various parameters, such as dots/second, volume/drop, number of ejection strokes, etc. As is known in the art and as taught in the specification, controlling the dot pattern, the size or shape of the dot, or the consistency of the size of the dots will inherently provide control over the dissolution rate. The precise nature of Voss' printing technique yields such control.

As for the newly-added limitation of first "identifying a target dissolution rate", Examiner notes that safe and effective administration of drug (bioactive agent) to a patient requires a precise does at an acceptable "target" dissolution rate. Medical professionals, such as doctors, pharmacists, and pharmaceutical company scientists, are of ordinary skill in this art. Medical personnel would have been aware that a too-rapid dissolution rate could lead to an over-dose, whereas a too-slow dissolution rate could lead to ineffective treatment levels. Neither of these risks is acceptable. Also, many medications are provided in a controlled release (CR) form to provide the correct dose over a period of time, inherently requiring the use of a target dissolution rate.

Therefore, when creating a drug delivery substrate, it is Examiner's position that it would have been inherent for one of ordinary skill in the art to identify, in addition to a desired target does, a target dissolution rate. The patterns of dots placed down on the delivery substrate of Voss would have been inherently placed to achieve said target dissolution rate for the safety and health of patients.

In the alternative, for all the reasons stated above, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to select a target dissolution rate to be achieved by the patterns of Voss to ensure the safe and effective administration of drugs to patients.

One of ordinary skill in the art would have been well aware of the effects of surface area on dissolution rate, for example, that a plurality of small, thin dots would dissolve faster than a thick, large dot of the same total volume. As evidence of this awareness, as outlined above, Voss teaches control of the parameters that would have been known by ordinary artisans in the medical coating art at the time the invention was filed to impact dissolution rate.

Voss' method produces less than 1% deviation from average (Ex. 3)

Voss teaches the use of a piezoelectric ejection element (abstract).

Voss provides the bioactive agent in a solvent (col. 5, lines 52-62), that inherently dries by evaporation, with precisely controlled concentration and drop volume (col. 6, line 5).

Regarding newly-added claim 25, while unclear, as outlined above, a pattern will inherently impact the dissolution rate speed.

Newly-added claims 26 and 28 are rejected for the same reasons as claim 1.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voss, as applied above, in view of Voges (5,894,841).

Examiner maintains the rejection of the previous office action, which is re-stated herein:

Voss teaches that which is disclosed above, namely forming droplets of bioactive agent using piezoelectric ejection elements. What Voss does not teach is the use of thermal ejection elements.

It is Examiner's position that these two species of inkjet printing are obvious variants that would have been known to an ordinary artisan and cites Voges for teaching the same.

Voges teaches a method of forming droplets of bioactive agent by using one of the two forms of inkjet printing, namely either a piezoelectric ejection device or a thermal ejection device.

Since Voss teaches printing precise drops of bioactive agent using a piezoelectric element, such as is used in inkjet printing, and Voges teaches that either the piezoelectric or thermal types of inkjet printing are suitable for forming precise droplets

of bioactive agent, Voges would have reasonably suggested the use of a thermal element in the method of Voss. It would have been obvious to one of ordinary skill in the art to use the interchangeability teachings of Voges in the method of Voss to provide Voss with a suitable, successful alternative element for dosing dots in a precise manner.

Response to Arguments

8. Applicant's arguments filed 6/2/2006 have been fully considered but they are not persuasive.

Examiner addresses Applicant's arguments in the body of the rejections, above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer K. Michener
Primary Examiner
Art Unit 1762